

REMARKS/ARGUMENTS

Claims 1-2 and 5-22 remain in this application.

Rejections Under 35 USC 103

Claims 1, 2, and 5-22 were rejected under 35 USC 103 as being unpatentable over Buxton et al. (US6428808) or Drake et al. (US2003/0026872) in view of Mathiowitz et al (US 4861627) or Porzio et al. (WO 97/13416). See Pages 2-5 of the Office Action.

Applicants respectfully disagree.

Independent claim 1 recites “A liquid pharmaceutical dosage form comprising a liquid matrix containing an active ingredient, a first flavoring agent having a first flavor, and a plurality of particles comprising a second flavoring agent having a second flavor wherein said particles comprise flaked films that are suspended in the liquid matrix. (emphasis added)” As argued in the previous amendment filed on June 27, 2007 (“Previous Amendment”), Buxton et al., Drake et al., Mathiowitz and Porzio all fail to disclose or suggest a liquid pharmaceutical dosage form.

Specifically, Buxton et al. discloses an “edible solid flavored substrate is preferably pharmaceutically acceptable and should be made of a material which dissolves or disperses rapidly in contact with the liquid material.” See col. 4, 47-49 of Buxton et al. However, nowhere in Brixton et al. does it disclose where the addition of such substrate would result in the claimed liquid pharmaceutical dosage form “comprising a liquid matrix containing an active ingredient, a first flavoring agent having a first flavor, and a plurality of particles comprising a second flavoring agent having a second flavor wherein said particles comprise flaked films that are suspended in the liquid matrix.” In other words, Buxton et al does not disclose where such substrate would disperse and suspend in the liquid material to form discreet flaked flavorant films. Rather, the substrate of Buxton et al. appears to either completely dissolve or merely disintegrate as non-flaked particles.

Drake et al. fails to disclose or even suggest a liquid pharmaceutical dosage form comprising an active ingredient let alone one “comprising a second flavoring agent having a second flavor wherein said particles comprise flaked films that are suspended.” Similarly, Mathiowitz and Porzio all fail to disclose or suggest a liquid pharmaceutical dosage form.

While the Office Action acknowledges this fact, it asserts without further substantiation that “it would have been obvious to one ordinary skill in the art to, by routine experimentation select flavoring agent in the form of flake film having the thickness that would fall within the claimed range.” Applicants, as discussed above, again respectfully disagree, as such a suspension is not taught nor suggested by any of the references.

In the Previous Amendment, Applicants noted that as discussed on page 11 and Example 2 of the specification, they had unexpectedly found that by using flaked film flavorants, such flavorants persisted in the oral cavity after swallowing such liquid pharmaceutical dosage. Specifically, as set forth in Example 2, (i) the customized dosage forms containing flaked films significantly reduced the aftertaste of Children’s Tylenol®, (ii) the customized Children’s Tylenol® provided a significantly longer lasting flavor experience, (iii) the children were able to distinguish two sequentially-distinct flavors in the customized Children’s Tylenol®, and (iv) the flaked films enhanced the overall palatability of Children’s Tylenol® suspension, leading to a more likeable taste.

In response to these arguments, the Examiner states that the “cited prior art teach the same unexpected results desired by the applicant. (emphasis added)” See page 4 of the Office Action. Applicants are unsure as to how these references could teach the unexpected benefits of using flaked film flavorants (as compared to one comprising just non-flaked flavorants), when the references do not even teach or suggest making such flaked film flavorant suspension. For example, as set forth in Example 2, Applicants found that a significantly larger percentage of children (69.2%) indicated that the customized Children’s Tylenol® had a longer lasting flavor than medicine they take without the flaked films.” Applicants respectfully disagree that the cited references could have teach this unexpected benefit when they fail to teach, or suggest, the use of flaked film flavorant suspensions.

Accordingly, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or

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suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP-5022/WEM.

Respectfully submitted,

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